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REMARKS

This is a full and timely response to the non-final Official Action mailed May 18, 2006. Reconsideration of the application in light of the following remarks is respectfully requested.

Claim Status:

Claims 1-31 are now pending for further action.

35 U.S.C. § 112, First Paragraph:

The recent Office Action rejected claims 22 and 23 as failing to comply with the written description requirement of 35 U.S.C. § 112, first paragraph. Applicant respectfully disagrees.

Claim 22, as amended, recites: "The method of Claim 18, wherein said stimulating comprises applying a series of inhibitory electrical stimulation pulses." This subject matter is clearly supported by a written description in Applicant's specification as originally filed at, for example, paragraph 0058. Paragraph 0058 states, in pertinent part, that "[i]nhibitory electrical stimulation [is] applied to sympathetic trunk 105 at spinal levels T1-T4 to block sympathetic efferents and afferents [which is likely to] prove efficacious in the treatment of angina pectoris." Clearly there is written description in the original application supporting claim 22.

Claim 23 recites "applying said series of inhibitory electrical stimulation pulses, sensing any change in sympathetic firing rate and adjusting electrical stimulation applied with said implanted stimulator in response to any sensed change in sympathetic firing rate." This subject matter is clearly supported by a written description in Applicant's specification as originally filed at, for example, paragraphs 0093-94. This portion of the application teaches that "[a]fter each

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stimulation pulse, series of pulses, or at some other predefined interval, any change in sympathetic firing rate is sensed. ... [S]timulator 150 [then] adjusts stimulation parameters automatically based on the sensed response.” Clearly there is written description in the original application supporting claim 23.

For at least these foregoing reasons, the rejection of claims 22 and 23 based on 35 U.S.C. § 112, first paragraph, should be reconsidered and withdrawn.

Applicant further notes that no rejection based on prior art was applied in the recent Office Action against claims 22 and 23. Consequently, claim 22 has been amended herein and rewritten as an independent claim. Therefore, following entry of this amendment, claims 22 and 23 should be in clear condition for allowance.

Prior Art:

Claim 28 was rejected under 35 U.S.C. § 102(b) as anticipated by U.S. Patent No. 5,334,221 to Bardy (“Bardy”). For at least the following reasons, this rejection is respectfully traversed.

Claim 28 now recites:

A method of using an implantable electrical stimulator to treat angina pectoris, comprising alleviating symptoms of said angina pectoris using said stimulator that *disrupts pain signals associated with angina pectoris by applying* electrical stimulation to any of afferent fibers along cardiac sympathetic nerves, stellate ganglia, afferent fibers along cardiac parasympathetic nerve fibers, superior cervical (vagal) cardiac nerve, interior cervical (vagal) cardiac nerve, atrioventricular node or ventricles.
(Emphasis added).

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Support for the amendment to claim 28 can be found in Applicant's originally-filed specification at, for example, paragraph 0062.

In contrast, Bardy fails to teach or suggest the claimed method of treating angina pectoris by disrupting pain signals associated with the angina by applying electrical stimulation to any of the specified nerves. Rather, Bardy teaches a device that treats angina by stimulating a nodal fat pad of the heart to cause a reduction in heart rate. "Stimulation of the SA nodal fat pad results in a reduction in the sinus rate. The invention therefore also includes a pacemaker to assure that the effects of fat pad stimulation do not result in an inadequate heart rate." (Bardy, col. 2, lines 32-35). Thus, Bardy teaches regulating heart function to treat angina rather than the method claimed by applicant that includes disrupting actual pain signals associated with the angina.

Additionally, Bardy does not appear to teach or suggest stimulating any of the specific nerve sites listed in claim 28. Rather, Bardy teaches stimulation the nodal fat pad of the heart. The recent Office Action does not indicate how or where Bardy teaches stimulating any of the claimed sites.

"A claim is anticipated [under 35 U.S.C. § 102] only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987) (emphasis added). See M.P.E.P. § 2131. For at least these reasons, the rejection based on Bardy should be reconsidered and withdrawn.

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Next, claims 9, 11, 13-18, 20, 21 and 28 were rejected under 35 U.S.C. § 102(a) as anticipated by WO 02/34330 to Hill et al. ("Hill"). For at least the following reasons, this rejection is also respectfully traversed.

Claim 9 recites:

A method for treating a patient with angina pectoris, comprising:
providing a miniature implantable stimulator with at least one electrode and with a size and shape suitable for placement of the at least one electrode adjacent to a nerve;
implanting the at least one electrode at nerve tissue influencing the angina pectoris of the patient, which tissue is at least one of an intercostal nerve and an intercostal nerve branch;
providing operating power to the stimulator;
using an external appliance to transmit stimulation parameters to the stimulator;
receiving the stimulation parameters at the stimulator;
generating stimulation pulses in accordance with the stimulation parameters, which pulses are generated by the stimulator;
delivering stimulation pulses via the stimulator and the at least one electrode to the at least one of the intercostal nerves and intercostal nerve branches influencing angina pectoris as a treatment for angina pectoris;
wherein delivering stimulation pulses further comprising generating and delivering excitatory stimulation pulses to at least one of the intercostal nerves and the intercostal nerve branches.
(Emphasis added).

In contrast, Applicant believes that Hill does not teach or suggest delivering excitatory stimulation pulses as recited in claim 9. Applicant notes that claim 9 recites "delivering excitatory stimulation pulses *to at least one of the intercostal nerves and intercostal nerve branches.*" (Emphasis added). Many stimulation systems apply inhibitory stimulation pulses to reduce nerve activity. Applicant is instead claiming excitatory stimulation pulses, i.e., pulses that excite nerve activity.

According to the Office Action, this subject matter is taught on page 22 of Hill. (Action of 5/18/06, p. 3). However, Applicant has reviewed this portion of Hill and does not believe it

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teaches delivering excitatory stimulation pulses as claimed. Hill merely teaches the stimulation of various sites, some of which are not even nerve tissue. Applicant does not believe that Hill suggests delivery of excitatory stimulation pulses to the nerves as recited in claim 9.

"A claim is anticipated [under 35 U.S.C. § 102] only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987) (emphasis added). See M.P.E.P. § 2131. For at least this reason, the rejection of claim 9 and its dependent claims should be reconsidered and withdrawn.

Claim 18 recites:

A method of using an implantable electrical stimulator to treat angina pectoris, comprising electrically stimulating an intercostal nerve or intercostal nerve branch with an implanted stimulator so as to treat said angina pectoris, wherein said stimulating comprising *electrical stimulation pulses at a frequency less than 100 Hz*. (Emphasis added).

In contrast, Hill does not teach or suggest a method of treating angina pectoris that includes stimulating with stimulation pulses at a frequency less than 100 Hz. "A claim is anticipated [under 35 U.S.C. § 102] only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987) (emphasis added). See M.P.E.P. § 2131. For at least this reason, the rejection of claim 18 and its dependent claims should be reconsidered and withdrawn.

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Independent claim 28 recites:

A method of using an implantable electrical stimulator to treat angina pectoris, comprising alleviating symptoms of said angina pectoris using said stimulator that disrupts pain signals associated with angina pectoris by applying electrical stimulation to any of afferent fibers along cardiac sympathetic nerves, stellate ganglia, afferent fibers along cardiac parasympathetic nerve fibers, superior cervical (vagal) cardiac nerve, inferior cervical (vagal) cardiac nerve, atrioventricular node or ventricles.

In contrast, Hill fails to teach or suggest stimulating any of the specific sites listed in claim 28 as part of a method of treating angina pectoris. Pages 4 and 8 of Hill teach various sites at which stimulation may be applied, including on the pectoral muscle and related structure. However, Hill does not teach or suggest stimulation as claimed in claim 28.

"A claim is anticipated [under 35 U.S.C. § 102] only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987) (emphasis added). See M.P.E.P. § 2131. For at least this reason, the rejection of claim 28 and its dependent claims should be reconsidered and withdrawn.

Claims 1, 2, 4-8, 19 and 24-27 were rejected as either anticipated under 35 U.S.C. § 102(a) or obvious under 35 U.S.C. § 103(a) in view of Hill, taken alone. For at least the following reasons, this rejection is respectfully traversed.

Claim 1 recites:

A method for treating a patient with angina pectoris, comprising:
providing a miniature leadless implantable stimulator with at least one electrode and with a size and shape suitable for placement of the entire stimulator adjacent to a nerve;

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implanting the stimulator adjacent to at least one tissue influencing the angina pectoris of the patient, which tissue is at least one of an intercostal nerve and an intercostal nerve branch;
providing operating power to the stimulator;
using an external appliance to transmit stimulation parameters to the stimulator;
receiving the stimulation parameters at the stimulator;
generating stimulation pulses in accordance with the stimulation parameters, which pulses are generated by the stimulator;
delivering stimulation pulses via the stimulator to the at least one of the intercostal nerves and intercostal nerve branches influencing angina pectoris as a treatment for angina pectoris.
(Emphasis added).

In contrast, Hill does not teach or suggest a method that includes "a miniature leadless implantable stimulator with at least one electrode and with a size and shape suitable for placement of the entire stimulator adjacent to a nerve," as claimed. To the contrary, for the most part Hill appears to teach away from this subject matter of claim 1. According to Hill, as seen in Fig. 1C, "implanted lead 106c is employed to deliver stimulation using a subcutaneous electrode that may be positioned under the skin using a 'tunneling' approach." (Hill, p. 9, last paragraph). Hill does not appear to teach any embodiments in which electrodes that are not on a lead provide stimulation to nerve tissue.

"A claim is anticipated [under 35 U.S.C. § 102] only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987) (emphasis added). See M.P.E.P. § 2131. "To establish prima facie obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974)." M.P.E.P. § 2143.03. Accord. M.P.E.P. §

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706.02(j). For at least these reasons, the rejection of claim 1 and its dependent claims should be reconsidered and withdrawn.

Intercostal Nerves:

In the recent Office Action, the Applicant was invited to further define on the record the term "intercostal nerve branches." Applicant respectfully declines to do so. The definition of a claim term is defined, first, by Applicant's specification and, second, by the commonly understood meaning of the term in the art. *Markman v. Westview Instruments*, 116 S. Ct. 1384 (1996); *Envirotech Corp. v. Al George, Inc.*, 730 F.2d 753, 759, 221 U.S.P.Q. 473 (Fed. Cir. 1984). Applicant, therefore, refers the Office to the specification and the meaning of "intercostal nerve branches" in the medical arts. To give any other response could result in prosecution history estoppel that is unnecessary and potentially detrimental to the scope of Applicant's claims.

Conclusion:

The newly added dependent claims 29-31 are thought to be patentable over the prior art of record for at least the same reasons given above with respect to the independent claims. Therefore, examination and allowance of the newly added claims is respectfully requested.

For the foregoing reasons, the present application is thought to be clearly in condition for allowance. Accordingly, favorable reconsideration of the application in light of these remarks is courteously solicited. If any fees are owed in connection with this paper, that have not been elsewhere authorized, authorization is hereby given to charge those fees to Deposit Account 18-


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0013 in the name of Rader, Fishman & Grauer PLLC. If the Examiner has any comments or suggestions which could place this application in even better form, the Examiner is requested to telephone the undersigned attorney at the number listed below.

Respectfully submitted,

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